



Department of Defense Biological Defense Program Needs for Strategic Biotechnology Development

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***BIO-Defense and Homeland Security
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The DoD Joint Chemical Biological Defense Plan (CBDP) Vision

Ensure U.S. military personnel are the best equipped and best prepared force in the world for operating in future battlespaces that may feature chemically and biologically contaminated environments.



Principles of Biological Defense

- ♦ **No single technology or set of procedures is sufficient to counter the threat of biological weapons.**
- ♦ **Military response is based on a *system of systems*, which are organized according to three principles:**
 - Contamination avoidance
 - Protection
 - Decontamination
- ♦ **Supported by a variety of tools:**
 - Modeling and Simulation
 - Warning and Reporting
 - Command and Control

Potential BW Agents

Bacteria/Rickettsia

Anthrax →



Brucellosis

Cholera

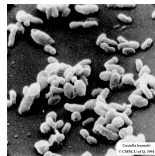


Plague →

Shigella

Tularemia

Q-Fever →



Typhus

Viruses

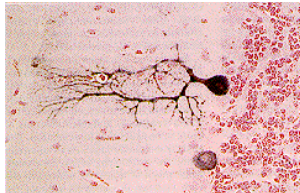
Smallpox

Rift Valley Fever

Crimean-Congo

Hemorrhagic Fever

VEE



Toxins

Botulinum



Ricin

SEB →



T2 Mycotoxins

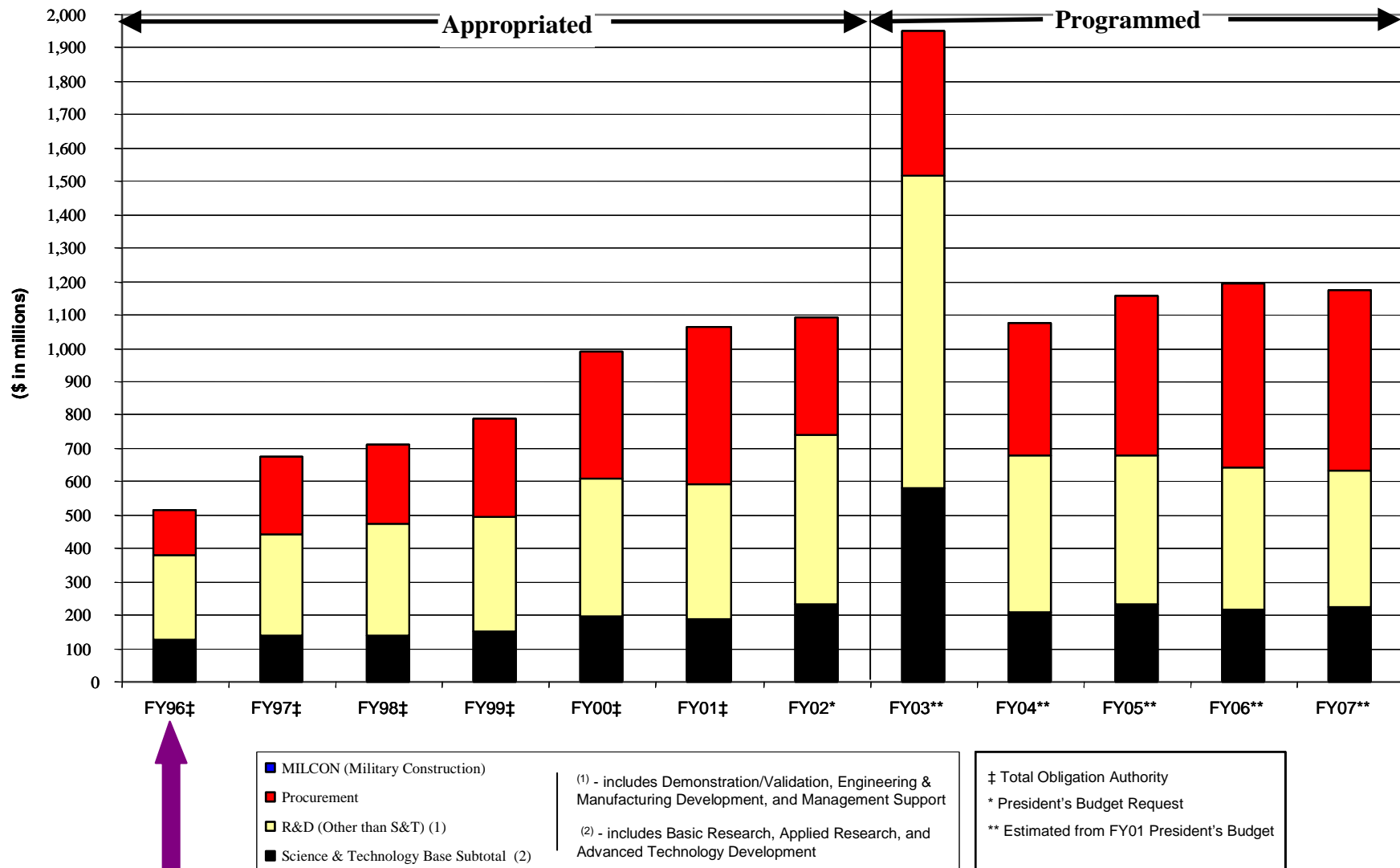
Saxitoxin

C. perfringens toxins

Neurotoxins

Aflatoxin

DoD CB Defense Program Historical Perspective- Funding

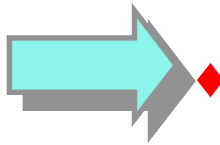


Note: \$.7M MILCON -FY02

\$ 5.0M MILCON- FY03

First PL 103-160 Consolidated POM submitted

Selected Program Highlights



Biological Defense

- Biodefense Vaccines
- Medical Biological Defense Research
- Non-Medical Biological Defense Research

♦ **Homeland Security Initiative**

- Office of Homeland Security
- DoD Consequence Management

Why Vaccinate?

- ◆ **Biological warfare (BW) agents pose high risk to military forces and operations**
 - At least 10 countries pursuing BW programs
- ◆ **Vaccines are lowest risk, most effective protection**
 - More effective with fewer adverse effects than antibiotics or other treatments
 - Enable force projection by providing continuous, long-lasting protection
- ◆ **DoD Policy (DoD Directive 6205.3)**
 - “...develop a capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threats.”
- ◆ **No real-time detection systems currently available**
 - Identification delayed 15-45 minutes after exposure
- ◆ **Masks must be worn to be effective**

Chronology of Considerations for Biodefense Vaccine Production

1991/92

June 93

Aug 94

Jan 95

1996



(Joint Program Office for Biological Defense Established)

GOCO



- *Why Started?* Lessons From Operation Desert Shield/Storm
 - No Surge Capacity for BD Vaccines
 - Limited Industry Interest
- *Why Stopped?* DOD and Congressional Directives
 - Need for Dedicated DOD Facility?
 - Most Economical Approach?



COCO



- *Why Modified?* Affordability
 - ADM Directed Cost/Benefit Analysis
 - \$450M Unfunded Requirement FY96-01
 - Industry Survey



Prime Systems Contract Approach

- *Why Started?* **Optimum Resource Utilization**
 - Reduces Requirement for New Facilitization
 - Enhances Competition
- Directed Prime Systems Contract Approach
- Prime System Contract Awarded (Nov-1997)

Concerns for Developing & Producing Biological Defense Vaccines

- ◆ **Limited interest from industry**
 - BD Vaccines similar to orphan drugs (interest from a few small to mid-size companies)
- ◆ **Identifying surrogate markers of efficacy**
 - Animal models used to validate efficacy of vaccines
 - Limited human efficacy data available
 - FDA review of 21 CFR requirement for Phase 3 efficacy testing in humans
 - May allow efficacy based on animal data (at least two species)
- ◆ **Large/complicated clinical studies to demonstrate safety, immunogenicity, and efficacy**

Concerns for Using Biological Defense Vaccines

- ♦ **Vaccine use: Routine use vs. stockpile**
 - Limited shelf life for stockpile
 - FDA issues for maintaining license if site not involved in ongoing production
- ♦ **Undetermined health effects of administering multiple vaccines**
 - No adequate basis to assess safety, yet no basis for extraordinary concern
 - *Interactions of Drugs, Biologics, and Chemicals in U.S. Military Forces* (1996) Institute of Medicine
- ♦ **Undetermined long-term health & safety effects**
- ♦ **Policy/Risk decision on vaccine types**
 - Live vaccines may be more effective, yet may have greater adverse effects (e.g., Oral vs. injectable polio vaccines)
- ♦ **No policy for immunizing civilian population**
 - Considerations include larger populations, pediatrics, geriatrics, immune-suppressed individuals

Selected Medical Biological Defense Research Initiatives

- ♦ **Multi-agent vaccines**
 - For various strains/serotypes
 - Multi-species (*e.g.*, MMR, DPT)
- ♦ **Therapeutics**
 - Especially for viral agents, toxins
 - Leveraging licensed products
 - Test and evaluation to support new labeling of licensed products for biodefense therapy (*e.g.*, Cipro)
- ♦ **Needle-less delivery**
 - Respiratory, oral, transdermal
- ♦ **Diagnostics**
 - Automated and rapid analysis
 - Rapid or automated sample preparation from multiple matrices (air; water; soil; blood, saliva, other tissue/fluids; *etc.*)

Selected Medical Biological Defense Research Initiatives

- ♦ **Countermeasures for Genetically Engineered Pathogens**
 - Genomic sequencing of BW threat agents to identify and understand virulence factors, toxins, and drug resistance genes
- ♦ **Immunomodulators**
 - Non-specific immunity as an alternative to vaccines
- ♦ **Demonstration of product efficacy**
 - Correlation between animal and human responses
 - Alternatives to animal models
- ♦ **Homeland security medical capabilities**
 - Evaluation to support use of vaccines and other countermeasures for non-military populations

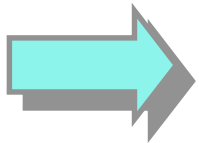
Selected Non-Medical Biological Defense Research Initiatives

- ♦ **Genetic detection methods**
 - Development and standardization of genetic probes/primers for PCR detection
- ♦ **Biological aerosol detection**
 - Near-real-time detection of pathogens in the air
- ♦ **Non-specific detection**
 - Activity-based detection based on physiological response rather than pathogen characteristics
- ♦ **Decontamination**
 - Building interiors
 - Sensitive equipment
 - Sampling and detection methods to confirm clean up

Selected Program Highlights

♦ Biological Defense

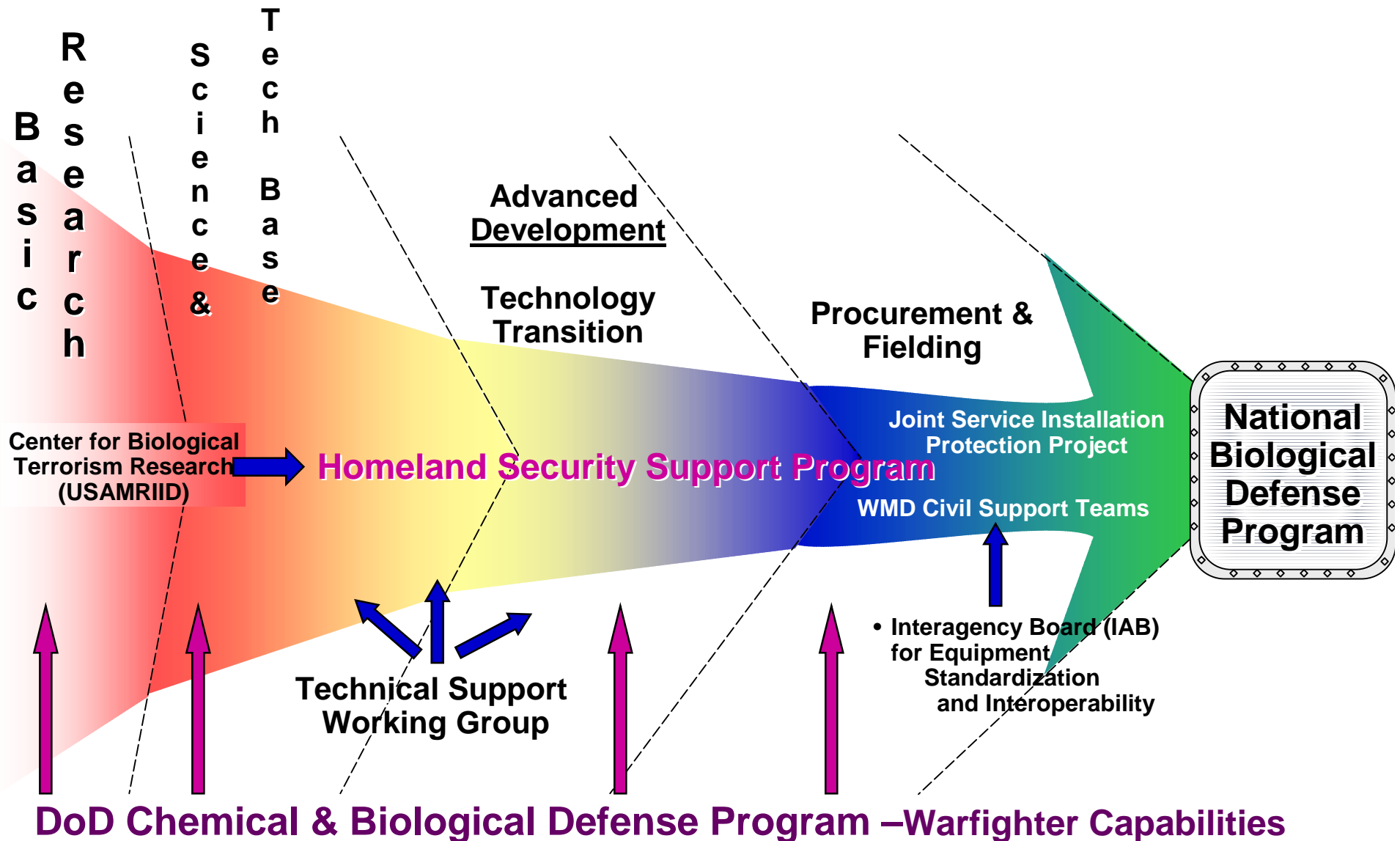
- Biodefense Vaccines
- Medical Biological Defense Research
- Non-Medical Biological Defense Research



♦ **Homeland Security Initiative**

- Office of Homeland Security
- DoD Consequence Management

DoD Homeland Security Programs for Biological Defense



Biological Counterterrorism Research Program

- ◆ Effort supported by Office of Homeland Security (OHS)
- ◆ Establishes a biological terrorism threat assessment research Center for Biological Counterterrorism at the U.S. Army Medical Research and Materiel Command, Fort Detrick:
 - Panel of senior scientists from DoD, federal labs, academia, industry and intelligence communities will develop concept and scope of threat assessment research
 - Research program will initiate competitive extramural contracts during design and construction phase

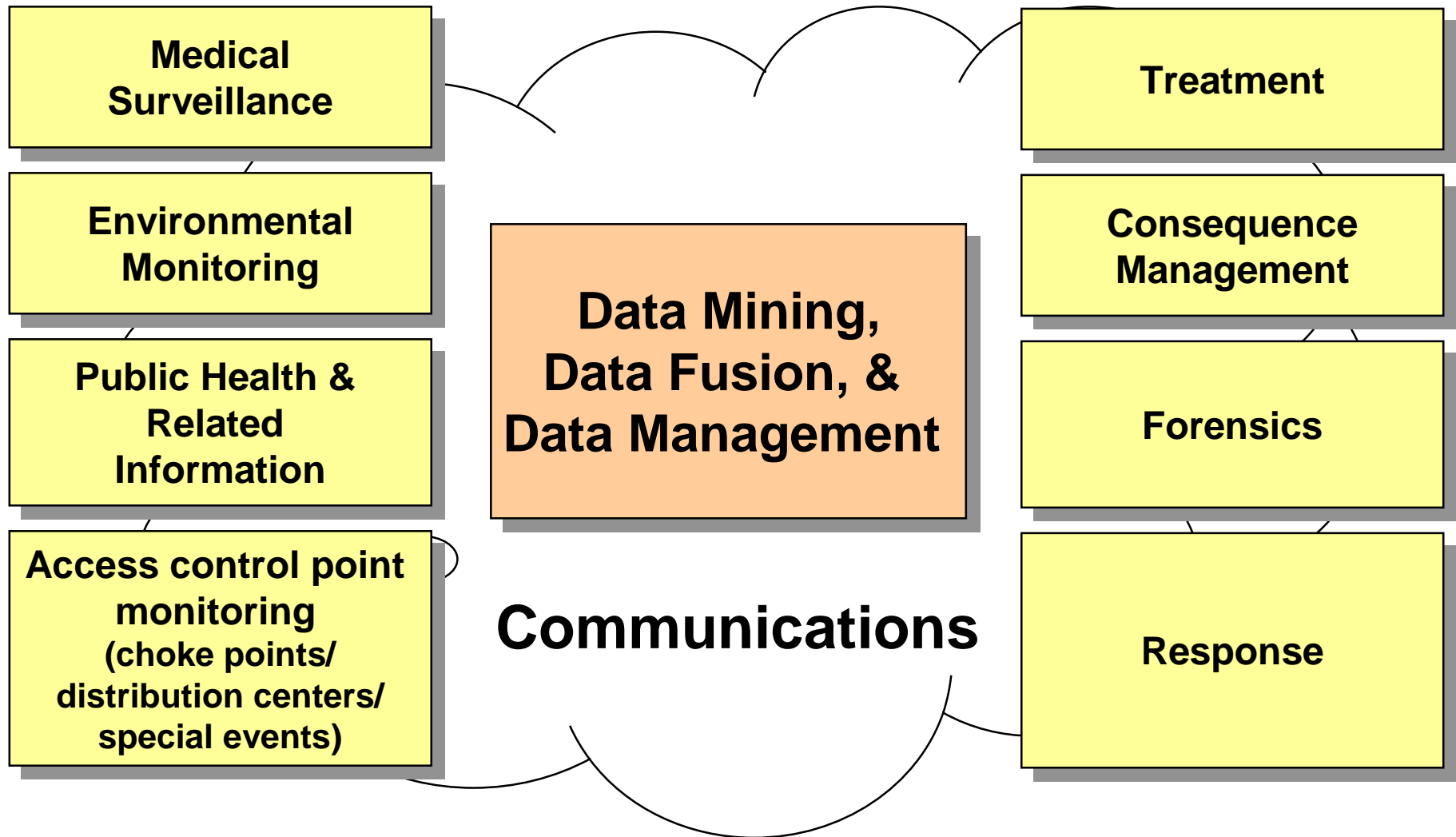
Biological Counterterrorism Research Program *(continued)*

- ◆ **Unique facilities will support DoD and national requirements for analysis of emerging biological threats and assessment of countermeasures against those threats**
- ◆ **FY03 Program will:**
 - Conduct technology survey and identify gaps
 - Award extramural research with emphasis on identification of virulence factors, pathogenic mechanisms and structural biology
 - Establish research programs in aerobiological research, forensic genomics and certified forensic biological threat agent capability
 - Initiate planning and concept development for dedicated facility to continue effort

Biological Defense Homeland Security Support Program

- ♦ **Initiates comprehensive program to build a National Biological Defense System for the Office of Homeland Security (OHS)**
- ♦ **Creates and deploys a national, multi-component, multi-organization defense capability targeted to urban areas, other high-value assets, and special events.**

Elements of a HLS Comprehensive System



Joint Service Installation Protection Project (JSIPP)

- ◆ **Pilot Project designed to increase CB Defense Capabilities at DoD Installations**
- ◆ **Project will equip 9 diverse DoD Installations with:**
 - State of the Art contamination avoidance, protection and decontamination equipment packages
 - Emergency response capability for consequence management
 - Integrated Command and Control Network
 - Comprehensive training and exercise plan



Consequence Management: WMD-Civil Support Teams

- ♦ **Funding in the DoD CBDP provides resources to complete fielding and modernization of:**
 - WMD- Civil Support Teams
 - Reserve Component (RC) Recon and Decon Teams
- ♦ **Program provides full funding for:**
 - Type-classified protection, detection, and training equipment
 - Development and fielding of upgraded analytical platforms for the detection, identification, and characterization of CB and radiological agents used by terrorists in a civilian environment
 - Development and fielding of communication capabilities that are interoperable with other federal, state, and local agencies
 - Testing and evaluation to ensure that the systems are safe and effective

Evolving Challenges

- ◆ **Supporting homeland security roles and missions**
 - Executing programs as strategy evolves
- ◆ **Enhancing CB installation force protection**
- ◆ **Acceleration of CB defense technologies**
 - Spinning off appropriate technologies for civilian applications
- ◆ **Maintaining current programs to respond to warfighter requirements**
 - Balance of competing priorities within current budget authority
- ◆ **Cooperation/strategy with HHS on Vaccine Development and Deployment**